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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,267	12/03/2001	Emil C. Gotschlich	040853-01-5029-02	8278

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EXAMINER

RAO, MANJUNATH N

ART UNIT PAPER NUMBER

1652

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/007,267

Applicant(s)

GOTSCHLICH, EMIL C.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 19 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 34-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 34-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 19 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 34-49 are still at issue and are present for examination.

Applicants' amendments and arguments filed on 3-13-03, paper No.7, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Based on applicant's arguments and acknowledging the filing of the terminal disclaimer, Examiner has withdrawn the rejection of claims under § 103(a) and under Obviousness type Double patenting rejection.

### ***Terminal Disclaimer***

The terminal disclaimer filed on 3-13-03 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Number 09/333,412 (now US 6,342,382) has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Drawings***

Formal drawings submitted on 3-13-03 in this application are accepted by the Examiner for examination purposes only.

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*Specification*

The amendment filed on 3-13-03, paper No. 7 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Applicants have made changes in several paragraphs of the application wherein they have changed the SEQ ID NO that were formerly assigned a specific function. According to the amendments filed, originally filed amino acid sequences no longer have the function previously associated with them. While the changing of amino acid sequence SEQ ID NO:2 formerly depicted as having glycosyltransferase to SEQ ID NO:3 is understandable (because originally SEQ ID NO:2 has been depicted as glycyl tRNA-synthetase  $\beta$  chain), changing the function of SEQ ID NO:3 to 8 is considered new matter by the Examiner. For example see the amendment filed for the paragraph on page 8, lines 14 to page 9 line 3. Originally, the specification indicated that SEQ ID NO:3 was responsible for adding Gal  $\beta 1 \rightarrow 4$  to GlcNAc or Glc comprising a mixture with an activated Gal to an acceptor comprising GlcNAc or Glc. However, applicants have now assigned that function to SEQ ID NO:8. Similarly on page 30, lines 11-29, originally the specification recited that SEQ ID NO:3 was involved in step (f) which would lead those skilled in the art to conclude that SEQ ID NO:3 catalyzed the transfer of activated Gal to the acceptor moiety comprising GlcNAc  $\beta 1 \rightarrow 3$  Gal  $\beta 1 \rightarrow 4$  Glc residue. However that activity has now been assigned to SEQ ID NO:8. Applicants do not provide any explanation as to why or how the activity associated with specific SEQ ID NO has now been changed. This constitutes new matter. Applicant is required to cancel the new matter in the reply to this Office Action.

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*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-39 and claims 40-49 which depend from claims 34-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 34-39 recite the phrase "a glycosyltransferase". However, the metes and bounds of this phrase is not clear to the Examiner. The term "glycosyltransferase" is a very broad name or a very general name for an enzyme. It is not clear to the Examiner as to how applicants differentiate the activities of the specific polypeptides claimed with other "glycosyltransferases" available in the prior art. These claims remain unclear until applicants define the specific glycosyltransferase activity of each polypeptide.

Claims 34-39 and claims 40-49 which depend from claims 34-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 34-39 recite the phrase "functionally active fragment thereof". Here again the metes and bounds of the phrase is not clear to the Examiner. Until applicants associate the specific glycosyltransferase activity of each of the polypeptide with its SEQ ID NO, the metes and bounds of the above phrase remains unclear to the Examiner. The specification lists specific transferase activity, i.e., in terms of the carbohydrate group that is transferred to specific acceptor moieties. However,

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none of such specific activities are associated with specific polypeptides in the claims.

Therefore, above claims are unclear to the Examiner.

In response to the previous Office action, applicants have traversed the above rejection arguing the invention is clearly defined in the specification and is differentiated with functionally inactive fragments. While such activities may be defined in the specification, claims are drawn to "glycosyltransferase activity" which is a general term applied in the art to identify a group of enzymes. As applicants have not associated specific glycosyltransferase activity to each of the claimed polypeptide, the phrase "functionally active fragment thereof" continues to be indefinite. Hence Examiner maintains the above rejection.

Claims 40-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 40-44 are drawn to a method of adding GalNAc or GlcNAc  $\beta$  1 $\rightarrow$ 3 to Gal comprising contacting a reaction mixture comprising an activated GalNAc or GlcNAc to an acceptor moiety comprising Gal in the presence of a glycosyltransferase. All the above claims are drawn to the same method involving the transfer of the same carbohydrate groups to the very same acceptor moieties but in the presence of different polypeptides. It is not clear to the Examiner as to whether all these polypeptides catalyze the very same reaction or different reactions involving different carbohydrate groups and different acceptor moieties as disclosed in the specification, rendering them indefinite.

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Claims 45-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 45-49 are drawn to a method of preparing an oligosaccharide having the structure  $\text{Gal}\beta 1 \rightarrow 4\text{Glc}$  to an acceptor moiety comprising a Glc residue in the presence of a glycosyltransferase. All the above claims are drawn to the same method involving the transfer of the same carbohydrate group to the very same acceptor moieties but in the presence of different polypeptides. It is not clear to the Examiner as to whether all these polypeptides catalyze the very same reaction or different reactions involving different carbohydrate groups and different acceptor moieties as disclosed in the specification, rendering them indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 34-49 are directed to polypeptides and their functionally active fragments corresponding to SEQ ID NO:2 through 6 and method of using such polypeptides. Claims 34-49 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of an amino acid residue in the respective SEQ ID NOS and fragments of said SEQ ID NOS that have not been disclosed in the specification. No description

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has been provided of all the polypeptide sequences encompassed by the claim. No information, beyond the characterization of their respective SEQ ID NOS has been provided by applicants which would indicate that they had possession of the claimed genus of polypeptides. The specification does not contain any disclosure of the function of all the polypeptide sequences including fragments and variants within the scope of the claimed genus. The genus of polypeptides claimed is a large variable genus including peptides which can have a wide variety of functions. Therefore many functionally unrelated polypeptides are encompassed within the scope of these claims. The specification discloses only single species identified by specific SEQ ID NO above which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

### ***Conclusion***

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications

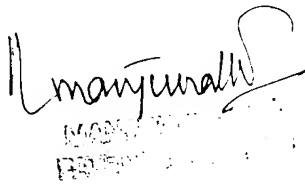


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and 703-308-4242 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.

A handwritten signature in black ink, appearing to read "Manjunath N. Rao". The signature is written in a cursive style with a large, looping initial "M". Below the signature, there is a faint, rectangular stamp that is mostly illegible but appears to contain the words "RECEIVED" and "MAY 30 2003".

Manjunath N. Rao  
May 30, 2003